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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/051,013	10/09/1998	TIMOTHY H. BESTOR	48075-B-PCT	7512

7590 05/21/2002  
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1185 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER
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STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/21/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/051,013

Applicant(s)

BESTOR, TIMOTHY H.

Examiner

David J. Steadman

Art Unit

1652

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26,29 and 34-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26,29 and 34-47 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Status of the Application***

The request filed on 02/25/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/051,013 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1-26, 29, and 34-47 are pending in the application.

Amendment to claims 1, 6, 11, 12, 15, and 24, cancellation of claims 27, 28, and 30-33 in Paper No. 11, filed 09/28/01 is acknowledged.

The instant application has been re-assigned to examiner David Steadman in Art Unit 1652. Contact information appears at the end of this Office action.

Upon reconsideration of the initial lack of unity of invention as set forth in Paper No. 5, filed 03/10/00, the examiner has elected to submit a new lack of unity of the pending claims.

### ***Lack of Unity***

1. Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- I. Claim(s) 1-4, 6-26, 29, and 42-46, drawn to a chimeric protein comprising a CpG-specific or *M. SssI* DNA methyltransferase with attenuated DNA binding activity and a zinc three-finger DNA binding protein, an expression vector encoding said chimeric protein, a method of inhibiting expression of a gene, and a pharmaceutical composition comprising said expression vector.
- II. Claim(s) 1-3, 5, 7-26, 29, and 42-46, drawn to a chimeric protein comprising a cytosine methyltransferase with attenuated DNA binding activity and a mutated LexA DNA binding protein, an expression vector encoding said chimeric protein, a method of inhibiting

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expression of a gene, and a pharmaceutical composition comprising said expression vector.

III. Claim(s) 34-41, drawn to a method of treating a subject infected with a virus by administering a chimeric protein.

IV. Claim(s) 47, drawn to a transgenic non-human mammal.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The chimeric protein of Group I, the chimeric protein of Group II, and the transgenic non-human mammal of Group IV are unrelated and chemically distinct entities and 37 CFR 1.475 does not provide for multiple independent products. The method of Group III does not share any technical feature with the transgenic mammal of Group IV and does not have unity of invention with the chimeric protein of Group I or II as the chimeric protein of Group I or II already includes a method of use of a chimeric protein, which comprises unrelated steps to the method of Group III and 37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention.

3. Because these inventions are distinct for the reasons given above and a different search is required for each of Groups I-IV, restriction for examination purposes as indicated is proper. "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02" (see MPEP 803). Each of the inventions listed as Groups I-IV requires a different patent and non-patent literature search.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(A) gene associated with a cancer

(B) gene associated with a central nervous system disorder

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- (C) gene associated with a blood disorder
- (D) gene associated with a metabolic disorder
- (E) gene associated with a cardiovascular disorder
- (F) gene associated with an autoimmune disorder
- (G) gene associated with an inflammatory disorder
- (H) gene associated with an infectious disease

5. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The following claim(s) is/are generic: claim 15.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the claimed disorders have different etiologies, therefore, the targeted genes associated with each disorder of (A)-(H) are likely to be distinct and would require targeting of different polynucleotide sequences, cells and tissues. Thus, different technical considerations would be necessary for targeting the different genes associated with the different disorders.

### ***Conclusion***


9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 2:00 pm and from 3:30 pm to 5:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

  
**REBECCA E. PROUTY**  
**PRIMARY EXAMINER**  
**GROUP-1800**  
• *1600*